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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	REDACTED - PUBLIC VERSION
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
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SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant/Counter-Plaintiff,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS
FROM SAREPTA REGARDING NS'S REQUEST
FOR LEAVE TO FILE AN AMENDED ANSWER TO SAREPTA'S COUNTERCLAIMS**

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Dear Judge Williams:

Sarepta respectfully opposes the request by Nippon Shinyaku (“NS”) for leave to amend its answer to add inequitable conduct allegations and *Walker Process* claims against the UWA patents. Such claims “plague not only the courts but also the entire patent system.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc). As explained below, NS’s proposed amendment should be denied for futility, prejudice, and lack of timeliness.

I. NS’s Proposed Inequitable Conduct Counterclaim and Defense Are Futile as a Matter of Law

A district court may deny a request for leave to amend if it is apparent from the record that the amendment would be futile. *Hill v. City of Scranton*, 411 F.3d 118, 134 (3d Cir. 2005). “Futility” means that the answer, as amended, would fail to state a claim upon which relief could be granted. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). In assessing futility, the district court applies the same standard of legal sufficiency as applied under Fed. R. Civ. P. 12(b)(6). *Id.*

Here, NS’s inequitable conduct allegations are futile as a matter of law. NS argues that the UWA patents cannot claim priority to the substantively identical UWA PCT application due to an alleged lack of written description support, and thus the “single most reasonable inference” is that the priority claim to that PCT application must have been fraudulent and deceptive. *See, e.g.*, D.I. 177-1 at ¶¶ 63, 88. According to NS, [REDACTED] could not have possessed the claimed genera as of the filing date of the PCT application because [REDACTED]. *Id.* at ¶ 62. NS further speculates, on information and belief, that [REDACTED] “did not know” whether the claimed oligonucleotides would work to induce exon skipping because [REDACTED]. *Id.* at ¶ 59.

It is hornbook law, however, that the written description requirement does not require actual construction of the invention (an “actual reduction to practice”). *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (“We have made clear that the written description requirement does not demand either examples or an actual reduction to practice”). Rather, the test for written description is “an objective inquiry into the *four corners of the specification* from the perspective of a person of ordinary skill in the art.” *Id.* Evidence as to whether the inventors actually reduced the invention to practice is not relevant to whether the four corners of the text provide adequate written description support. *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1286 (Fed. Cir. 2012) (that an inventor did not make certain embodiments within the scope of the claims “is not relevant to the written description inquiry,” because to satisfy written description, one must show only that “the specification itself demonstrates a constructive reduction to practice”). Here, the USPTO Examiner favorably evaluated both the priority claim and written description support for the UWA patent claims. *See* MPEP § 706.03 (the Examiner is required to assess all statutory requirements).

Although NS attempts to transform its misguided written description invalidity position into an allegation of inequitable conduct, it fails to plead facts necessary to support its case. NS does not plead any specific misrepresentation or omission that influenced the Examiner’s evaluation of written description. *See, e.g.*, D.I. 177-1 at ¶¶ 40-92. Instead, NS alleges that [REDACTED]

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██████████. *Id.* at ¶¶ 80-82. Written description, however, is assessed based on the **four corners of the patent specification**. *Ariad*, 598 F.3d at 1352. The futility of NS’s inequitable conduct theory is illustrated by its own patents. Six of NS’s patents asserted in this case do not exemplify even a single species within the scope of the claims, and discovery has shown that ██████████

██████████. Yet NS obtained and then asserted those patents in this litigation—claiming priority to that PCT application.¹

Unsurprisingly, numerous courts have rejected similar attempts to conflate written description and inequitable conduct. In *Impact Engine*, the court struck an inequitable conduct defense that alleged lack of written description support in an earlier-filed, substantively identical priority application—stating that it would “not expand the affirmative defense of inequitable conduct” to embrace this “novel theory.” *Impact Engine Inc. v. Google LLC*, 3:19-cv-01301-CAB-BGS, 2020 WL 3414627, at *2 (S.D. Cal. June 22, 2020). Similarly, in *Novozymes*, the court rejected an inequitable conduct allegation that was a mere “repackaging of [defendants’] argument regarding the adequacy of the written description.” *Novozymes A/S v. Danisco A/S*, No. 10-cv-251-BBC, 2011 WL 13210084, at *12 (W.D. Wis. July 7, 2011) (vacated in part on reconsideration on other grounds) (holding that an argument for lack of written description absent claims of specific misrepresentation “is a legal conclusion and not a proper claim for inequitable conduct”). And in *Purdue Pharma*, the Federal Circuit rejected an allegation of inequitable conduct premised on claiming priority to a substantively identical earlier filed application. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1367 (Fed. Cir. 2001) (“We therefore decline to find inequitable conduct in the mere act of claiming priority to an earlier patent where the specifications, but not the claims, of the later patents are supported by the earlier patent.”).

NS’s cited *Nilssen* case is readily distinguishable. In *Nilssen*, a patent’s priority dates were intentionally manipulated by making impermissible priority claims to prior applications that were not co-pending—a clear violation of USPTO rules, which require co-pending applications. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1228, 1233 (Fed. Cir. 2007); 37 C.F.R. § 1.78. No such facts are alleged here. Additionally, *Nilssen* predated the *en banc* Federal Circuit’s *Therasense* decision, which reset the inequitable conduct standard, and a later Delaware court held in a case litigating the same patents that “Mr. Nilssen’s faulty patent ancestry would not support a finding of inequitable conduct under the current law.” *CFL Techs. LLC v. Osram Sylvania, Inc.*, No. 18-1445-RGA, 2019 WL 2995815, at *7 (D. Del. July 9, 2019). Because NS’s proposed amendment advances a counterclaim and defense that are legally insufficient on their face, leave to amend should be denied. *Koken v. GPC Int’l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006) (internal citations and quotations omitted); Fed. R. Civ. P. 15(a).

II. NS’s Inequitable Conduct Counterclaim and Defense Fail To Meet the Rule 9(b) Standard

NS’s amendment should also be denied because NS failed to plead with the necessary particularity under Fed. R. Civ. P. 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). NS was required to identify “the specific **who, what, when, where, and how** of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327

¹ Although Sarepta disagrees that NS should be granted leave to amend, Sarepta reserves the right to assert additional defenses and counterclaims, as appropriate, in its subsequent answer if the Court grants NS’s motion.

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(emphasis added). This standard requires “sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328-29. Although “knowledge” and “intent” may be averred generally in a pleading, the pleading must contain “sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind” or else it fails to state a claim. *Id.* at 1327.

NS fails to identify any specific individual or individuals *who* allegedly misrepresented or omitted material information, instead referring to everyone theoretically involved in prosecution of the patents: [REDACTED] all of the prosecuting “Attorneys,” and unnamed “individuals at UWA and Sarepta who were involved in the preparation or prosecution of the UWA Applications.” *See, e.g.*, D.I. 177-1 at ¶¶ 73-76, 79-84. But a “broadly cast net around the inventors and those acting on their behalf . . . does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had specific intent to deceive the PTO.” *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013) (finding that defendant failed to satisfy the *Exergen* pleading standard regarding “who” deceived the PTO); *see also INVISTA N. Am. S.à.r.l. v. M&G USA Corp.*, No. 11-1007-SLR-CJB, 2013 WL 12304544, at *13 (D. Del. May 3, 2013) (denying leave to add allegations “never connecting specific conduct . . . to a specific individual or individuals”); *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 381 (D. Del. 2012) (same). Because NS’s general allegations cast an overly broad net, they do not meet the specificity requirements of Rule 9.

NS also does not plead *what* alleged misrepresentation or omission influenced the Examiner’s evaluation of written description. *See, e.g.*, D.I. 177-1 at ¶¶ 40-92. The [REDACTED] are not material to assessing written description support in the UWA PCT application. *See* § I, *supra*. Significantly, the two publications relied upon by NS in its allegations—Sazani and Watanabe (¶¶ 83-87)—*were* both considered by the USPTO and are listed on the face of the UWA patents. *See* ’827 Patent at 2; ’590 Patent at 2; ’851 Patent at 2. NS also points to certain statements made during prosecution to overcome obviousness rejections. D.I. 177-1 at ¶¶ 51-52. But the USPTO Examiner had these statements, the publications alleged to be relevant, *and* the as-filed specification of the PCT application—and determined that there was adequate written description to support the allowed claims. *See Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 310 (D. Del. 2004), *aff’d*, 488 F.3d 982 (Fed. Cir. 2007) (“In determining patentability, examiners consider references that are before them”); MPEP § 2103.

NS’s allegations also fail *Exergen*’s particularity requirement for scienter. Reflecting the factual deficiencies of its allegations, NS repeatedly uses the phrase “information and belief” in its pleading, including for allegations of intent. For example, NS states that “[u]pon information and belief, [REDACTED] and the Attorneys, along with any at Sarepta involved in the filing and prosecution of the UWA Applications, deliberately submitted false information and withheld information material to patentability with deceptive intent to obtain allowance of the Sarepta Asserted Claims.” D.I. 177-1 at ¶ 82. The Federal Circuit has expressly limited when deceptive intent can be pled “on information and belief” to cases where “the pleading sets forth the specific facts upon which the belief is reasonably based.” *Exergen*, 575 F.3d at 1330. NS’s new allegations lack any such factual predicate upon which its averment of intent can be reasonably based, and thus NS cannot plead intent based only “on information and belief.”

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The particularity requirement of Rule 9(b) “would be meaningless” if “bare bones inequitable conduct claims,” such as this one, “stand as pled.” *Lannett Co. v. KV Pharms.*, No. 08-338-JJF, 2008 WL 4974579, at *4 (D. Del. Nov. 21, 2008). NS’s inequitable conduct allegations are insufficient and therefore futile, and NS should not be granted leave to amend.

III. NS’s Proposed *Walker Process* Antitrust Counterclaim Is Futile

NS’s proposed *Walker Process* counterclaim is also futile because it fails to state a claim upon which relief can be granted. *Koken*, 443 F. Supp. 2d at 634. To prevail on a *Walker Process* claim based on the alleged maintenance and enforcement of a fraudulently obtained patent, “the antitrust-plaintiff must show two things: first, that the antitrust-defendant obtained the patent by knowing and willful fraud on the patent office and maintained and enforced the patent with knowledge of the fraudulent procurement; and second, all other elements necessary to establish a Sherman Act monopolization claim.” *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016). Therefore, NS must adequately plead both *Walker Process* fraud—which, like inequitable conduct, is subject to Rule 9(b)’s standards—**and** all the elements of an antitrust violation. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev’d on other grounds*, 549 U.S. 118 (2007). NS’s *Walker Process* claim fails on both counts.

As to the first element of *Walker Process* fraud, NS concedes that its antitrust claim wholly depends on its inequitable conduct claim, which is defective. D.I. 178 at 3. Its motion to amend should therefore be denied for the same reasons addressed above. *EIS, Inc. v. WOW Tech Int’l GmbH*, C.A. No. 19-1227-LPS, 2020 WL 7027528, at *12 (D. Del. Nov. 30, 2020) (“Having found that the inequitable conduct claims must be dismissed, the *Walker Process* fraud claim—which is predicated on the inequitable conduct claims—must likewise be dismissed.”).

NS’s allegations as to the “other elements” of its attempted monopolization claim are equally defective. The antitrust elements of a *Walker Process* claim include: “(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *TransWeb*, 812 F.3d at 1306 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)). NS’s conclusory allegations fail to allege sufficient factual content to state a viable claim under Rule 12. For example, in support of the second element, NS simply alleges that “Sarepta has engaged in predatory or anticompetitive conduct with a specific intent to monopolize by attempting to enforce the UWA Patents against [NS],” with no facts to support this claim—and notwithstanding that NS initiated this suit. *See* D.I. 177-1 at ¶ 100. Such “threadbare recitals of the elements of a cause of action” must be disregarded in analyzing whether a claim meets the Rule 12(b)(6) standard. *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012).

NS’s proposed *Walker Process* claim is also futile because Sarepta is entitled to *Noerr-Pennington* immunity from antitrust liability because NS, not Sarepta, filed this case asserting a declaratory judgment claim, and Sarepta’s counterclaim for infringement is not objectively baseless. *See United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 13-16 (Fed. Cir. 2018). Further, even if NS’s fraud allegations were true—and they are not—Third Circuit precedent expressly declines to recognize a “misrepresentation” exception to *Noerr-Pennington* immunity. *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999) (“We decline to carve out a new exception to the broad immunity that *Noerr-Pennington* provides.”).

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IV. NS's Motion Is Prejudicial and Untimely

Sarepta will suffer undue prejudice if NS's motion is granted. *See Hill*, 411 F.3d at 134 (explaining that a district court may deny leave to amend if “the amendment would prejudice the other party”). This factor “requires [the Court to] focus on the hardship to the defendants if the amendment were permitted.” *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001) (internal citation and quotation marks omitted). Prejudice can include surprise, additional discovery, and increased litigation cost. *See id.* All of those factors showing prejudice are present here.

NS's newly introduced defense and counterclaims—raised immediately before the deadline to file its motion—would significantly expand and complicate the case. *See Randolph v. Wetzel*, 764 F. App'x 240, 243 (3d Cir. 2019) (affirming district court's denial of motion to amend when the motion “sought to significantly expand the scope of this case, and was filed after discovery had commenced”). The amendment, if allowed, would likely necessitate delays to the case schedule, require many additional fact and expert witnesses, and increase legal spend. Further, the complex financial discovery required by an antitrust claim is in no way “commensurate” with the existing suit, as NS alleges.² D.I. 178 at 2. And the issues raised by NS's amendment will confuse the jury, weighing in favor of denial. *See* 6 FED. PRACTICE & PROCEDURE CIV. § 1487 (3d ed. 2016) (“[If] the issues raised by the amendment are remote from the other issues in the case and might confuse or mislead the jury, leave to amend may be denied.”). Such a burden on the parties and the Court, particularly when coupled with the futility of the amendments, supports denial of NS's motion.

NS also filed its motion *on the last day allowed by the Court's scheduling order* despite being in possession of the UWA patents (and their public file histories) for years, and the laboratory notebooks for months. NS first notified Sarepta of its inequitable conduct claim three days before filing its motion and of its antitrust claim on an ensuing meet-and-confer just *one day* before filing. NS's delay exacerbates the burden on the Court and the undue prejudice to Sarepta that would result from the amendment. *See Cureton*, 252 F.3d at 273. As explained above, NS's delay in filing its motion until the last possible day—seeking to vastly expand the issues in this case when discovery is well underway—supports denial of NS's motion.

V. Conclusion

The facts as alleged by NS do not and cannot support its claims of inequitable conduct and *Walker Process* fraud. *See Burlington Coat Factory*, 114 F.3d at 1435 (“Therefore, to the extent we can affirm the district court's determinations on Rule 12(b)(6) grounds alone (i.e., for futility), we shall affirm the denial of leave to replead. These claims would not survive a Rule 12(b)(6) motion even if pled with more particularity.”). Sarepta therefore respectfully requests that the Court deny NS's motion without leave to amend.

² For example, determining the “dangerous probability of achieving monopoly power” for antitrust element (3) of a *Walker Process* claim “requires inquiry into the relevant product and geographic market and the defendant's economic power in that market.” *Spectrum Sports*, 506 U.S. at 459. This discovery differs from typical patent damages discovery in degree and in kind.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)